**Remarks/Arguments:**

This Amendment is in response to the Office Action dated October 4, 2006. Claims 10, 23, and 27-43 are withdrawn. Claims 1 and 14 are amended. New claims 44 and 45 are added.

Support for the amendment of claims 1 and 14 may be found at paragraphs 8, 55-56, 61-63, and 102 of US 2005/0079175, (the published application).

Support for new claims 44 and 45 may be found at paragraphs 11, 16, 18, 66-69, 91-92, and 95 of US 2005/0079175.

## I. CLAIM REJECTIONS

### A. 35 USC § 112 Enablement

All pending claims stand rejected for failing to comply with the enablement requirement. The Office Action contends that the scope of the claims is broader than the disclosure in the specification, because (1) applicant has not shown that the method is 100% effective in 100% of patients, and (2) the "agent" could be an inhibitor that does not bind IgE or FcεRII, such as antisense RNA. According to the Office Action, the scope of the term "agent" is too broad and it would require undue experimentation to identify such agents.

#### 1. Method is not 100% effective in 100% of patients.

According to the Office Action, the "broadest reasonable interpretation" of the phrase "preventing induction of the asthmatic state," from claim 1, is that the method is 100% effective in 100% of patients. Applicants respectfully disagree. "The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." (MPEP § 2111 citing *In re Cortright*, 165 F.3d 1353,1359, in which construction of "restore hair growth" was determined to mean "some increase in hair growth," but does not mean "hair returned to its original state.")

One of ordinary skill in the art, who is likely to be a medical or pharmaceutical professional, would not interpret "an agent preventing induction of the asthmatic state" to require 100% efficacy in 100% of patients. No medication or therapeutic treatment is 100% effective in 100% of patients.

The standard for determining the enabled scope of a claim is that "claims are to be given their broadest reasonable interpretation that is consistent with the specification," MPEP 2164.08, and "the teachings of the specification must not be ignored..." *Id.* The specification does not state or infer that the claimed method is 100% effective.

Nonetheless, to further the prosecution of their claims, Applicants have amended claim 1 by replacing "preventing" with "inhibiting," a term which does not connote 100% effectiveness.

2. Scope of the term "agent" is too broad.

Claims 1 and 14 have been amended to clarify that the inhibitory agent is an agent that binds to FcεRII receptor protein and, as a result, prevents binding between IgE and FcεRII. This amendment narrows the scope of "agent" to agents which bind FcεRII. New claim 44 is directed to a method that also encompasses nucleotides that encode such an agent. Enabling descriptions of such agents and nucleotides may be found in the specification at paragraphs 55, 61-64, 91, 94-95, 101-102.

The Office Action maintains that, because the specification states that the method encompasses agents that are as yet unknown ligands of FcεRII, it would require undue experimentation to disclose agents that bind to IgE or FcεRII. It is further argued that because the composition and structure of these unknown ligands is not known, the uses of these ligands cannot be known.

"There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper." MPEP 2173.05(g). It is proper to use functional language in a claim if it sets "definite boundaries on the patent protection sought." *Id.* The amended claims recite a method using an agent that binds to FcεRII receptor protein, and, as a result, prevents binding between IgE and FcεRII. This language sets definite boundaries on the scope of the agent used in the claims. IgE binding inhibition assays are described in the specification at paragraphs 64-65 and in original claim 27.

Furthermore, one of ordinary skill in the art could easily identify agents described by the amended claims using routine, well-known assays. Antibody-binding and receptor-binding assays are well known in the art and are routinely performed to determine specificity and strength (affinity) of binding between ligands and receptors, antibodies and antigens, etc., *e.g.*,

Scatchard analyses and immunoassays. These analyses are so routine in the art that they have been automated. One of ordinary skill in the art would know that such methods can be used to identify agents which bind to FcεRII and interfere with binding between IgE and FcεRII. It is unnecessary to know the structure or composition of such an agent to determine whether it binds to FcεRII and subsequently interferes with binding between IgE and FcεRII. The putative agent is merely subjected to routine testing to determine if it is appropriate for the claimed method.

For the above reasons, Applicants maintain that the pending claims, 1-9, 11-22, and 24-26, and new claims 44 and 45 are enabled.

**B. 35 USC § 112 Written Description**

Claims 1-5, 7-9, 11-18, 20-22, and 24-26 are rejected as failing to comply with the written description requirement, because, according to the Office Action, the term, "agents" encompasses anything that inhibits interaction between IgE and FcεRII and the breadth of this term is not supported by the specification.

Independent claims 1 and 14 have been amended to clarify that the inhibitory agent is an agent that binds to FcεRII receptor protein and prevents binding between IgE and FcεRII. New claims 44 and 45 are directed to a nucleotide sequence that encodes an agent that binds to FcεRII receptor protein in order to prevent binding between IgE and FcεRII. Such agents are described in the specification at paragraphs 55, 61-64, 91, 94-95, 101-102.

For these reasons, Applicants submit that claims 1-5, 7-9, 11-18, 20-22, 24-26, 44, and 45 meet the written description requirement of Section 112.

**C. 35 USC § 102**

Claims 1-9, 12-22, 25, and 26 are rejected under 35 USC § 102(e) as anticipated by Reff *et al.*, U.S. Pat. No. 6,011,138.

This rejection was also raised during prosecution of the parent application, now U.S. Pat. No. 6,630,140. Applicants successfully established, through a Supplemental Response Under 37 CFR 1.111, dated April 19, 2001, that their invention predates Reff, and, accordingly,

established that Reff is not prior art to this application. A copy of this Supplemental Response is enclosed with the Amendment.

Because Reff is not prior art to this application, claims 1-9, 12-22, 25, and 26 are not anticipated by Reff.

**D. 35 USC § 103(a)**

1. Reff/Cockroft

Claims 1, 11, 14, and 24 are rejected under 35 USC 103(a) as obvious over Reff in view of Cockcroft.

As discussed above, Reff is not prior art to this application. Cockroft discloses administration of well known anti-asthmatic agents and multiple anti-asthmatic agents in combination. However, Cockroft does not disclose a method for inhibiting induction of an asthmatic state or diminishing symptoms of asthma in a human patient comprising administering to said human patient an agent which binds to an FcεRII receptor protein, wherein said binding of said agent inhibits binding of IgE to the FcεRII receptor protein, said agent being suspended in a pharmaceutically acceptable carrier in an amount sufficient to inhibit said binding of IgE to the FcεRII receptor protein, thereby inhibiting the induction of said asthmatic state in said human patient, and thus does not teach all elements of the claimed invention. Therefore, claims 1, 11, 14, and 24 are not obvious over Reff in view of Cockroft.

2. Flores-Romo/Mosley

Claims 1-9, 12-22, 25, and 26 are rejected as obvious over Flores-Romo in view of Mosley.

Flores-Romo teaches that FcεRII "participates in the regulation of IgE synthesis" and speculates that it "could be important in allergic disease," (Abstract). By binding to FcεRII on B cells, the disclosed antibody is thought to block the interaction between B cells and T cells that is necessary to stimulate synthesis of IgE (page 1040, columns 2-3). Flores-Romo does not teach an antibody that binds to FcεRII and prevents binding of IgE to FcεRII, and does not teach

that an antibody that binds to FcεRII and prevents binding of IgE to FcεRII can be used to inhibit induction of asthma or treat asthma.

Mosley teaches that administration of soluble IL-4 receptors can suppress immune or inflammatory responses. The Mosely reference is directed specifically to IL-4 receptors and the effects of IL-4 on B cells. Mosely speculates that IL-4 receptors may be used in allergy therapy, because IL-4 receptors inhibit B-cell proliferation and IgE is produced by B-cells (Col. 16, lines 30-43). Mosely does not teach an antibody that binds to FcεRII and prevents binding of IgE to FcεRII, and does not teach that an antibody that binds to FcεRII and prevents binding of IgE to FcεRII can be used to inhibit induction of asthma or treat asthma.

Neither Flores-Romo nor Mosely discloses a method for inhibiting induction of an asthmatic state in a human patient comprising administering an agent which binds to an FcεRII receptor protein and inhibits binding of IgE to the FcεRII receptor protein and thus do not teach all elements of the claimed invention. The Office Action avers that by suppressing production of IgE and FcεRII, binding would necessarily also be suppressed. However, the agents disclosed in these references only decrease the amounts of IgE and FcεRII available for binding. They do not interfere with the actual binding of IgE to FcεRII as required by the instant claims. Therefore, claims 1-9, 12-22, 25, and 26 are not obvious over Flores-Romo in view of Mosely.

3. Flores-Romo/Mosley/Cockroft

Claims 11 and 24 are rejected as obvious over Flores-Romo in view of Mosley and Cockcroft. As discussed in the previous section, the claimed invention is not obvious over Flores-Romo in view of Mosley, because, even in combination, these references do not disclose all elements of the claimed invention. Cockroft does not provide these missing elements

Cockroft discloses administration of well-known anti-asthmatic agents and multiple anti-asthmatic agents in combination. Cockroft does not disclose a method for inhibiting induction of an asthmatic state or diminishing symptoms of asthma in a human patient comprising administering an agent which binds to an FcεRII receptor protein and inhibits binding of IgE to the FcεRII receptor protein. Therefore, claims 11 and 24 are not obvious over Flores-Romo in view of Mosely and Cockroft.

**E. Double Patenting**

Claims 1-9, 11-22, and 24-26 are rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-24 of U.S. Pat. No. 6,630,140. According to the Office Action, the patented claims are narrower in scope than the instant claims, and therefore anticipate the instant claims.

Applicants have amended claims 1 and 14 and prosecution of the application is still ongoing. Applicants will defer a decision whether to file a terminal disclaimer until the final form of the claims has been determined.

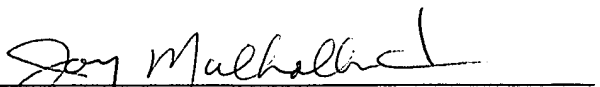
## II. RESTRICTION REQUIREMENT

Applicants maintain traverse of the restriction requirements and species election for the reasons given in the Response dated July 14, 2006.

## CONCLUSION

For the reasons given above, Applicants submit that claims 1-9, 11-22, 24-26, 44 and 45 are patentable and in form for allowance.

Respectfully submitted,



Christopher A. Rothe, Reg. No. 54,650
Joy Mulholland, Reg. No. 47,810
Attorneys for Applicant

JM/lrb

Attachment: Copy of Supplemental Response Under 37 CFR 1.111

Dated: January 4, 2007

P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

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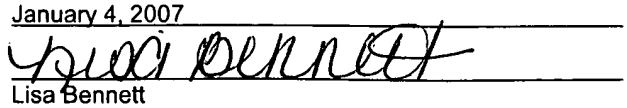

Lisa Bennett